## REMARKS UNDER 37 CFR § 1.111

## **Formal Matters**

Claims 1-4, 6-19, 23, 25-30 and 33-43 are pending after entry of the amendments set forth herein.

Claims 1-40 were examined. Claims 1-40 were rejected.

Applicant respectfully requests reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

## The Office Action

In the Official Action of November 1, 2005, claims 1-2, 4-11, 15-22, 24-30, 32 and 35 were rejected under 35 U.S.C. Section 102(b) as being anticipated by Buckman, Jr. et al., U.S. Patent No. 5,484,391. The Examiner asserted that Buckman, Jr. et al. discloses a device in Fig. 6 having an inflatable annular member 82 with a central opening (space 76) and an organ contacting surface 86. In view of the above amendment of claim 1, Applicant respectfully submits that Buckman, Jr. et al. fails to disclose an opening, as claimed. Claim 1, as amended, recites an opening that passes through the claimed inflatable member. It is respectfully submitted that the space 76 of Buckman, Jr. et al. that was identified by the Examiner is closed off by the walls 84 of the cup and the diaphragm 86, see column 9, lines 50-52. Accordingly, it is respectfully submitted that claim 1 and claims depending therefrom are not anticipated by Buckman, Jr. et al.

As amended, claim 25 recites, *inter alia*, applying a vacuum to the organ through an opening in the inflated member, while maintaining the inflated member in the inflated configuration, to create an intimate engagement between the organ and the inflated member. Since Buckman, Jr. et al. fails to provide an opening through which to apply vacuum to an organ, for reasons described above, it is respectfully submitted that Buckman, Jr. et al. fails to anticipate the step identified above. Further, vacuum cannot be applied to the device of Buckman, Jr. et al. without retracting or deflating the walls 84 of the cup.

The Examiner further asserted that Buckman, Jr. et al. discloses a cushioning compliant material that is configured to conform to and diffuse suction exerted on the organ. The Examiner referred to

column 6, lines 55-59 and 64-67 as support for these assertions. Applicant notes that column 6, lines 55-59 and 64-67 of Buckman, Jr. et al. refer to the cushioning material 18 on the contact surface of the device of Figs. 1-3, and that this device does not apply vacuum. Accordingly, it is respectfully submitted that Buckman, Jr. et al. does not teach or disclose diffusing suction exerted on an organ, contrary to the Examiner's assertions. Further, claim 7 has been amended to recite that the vacuum distribution element fluidly interconnects the recited lumen and the opening, and this feature is neither disclosed nor suggested by Buckman, Jr. et al.

Further, with regard to claim 9, Buckman, Jr. et al. fails to disclose or suggest an attachment element interconnecting an inflatable member and a positioning element, wherein the attachment member fluidly seals a connection of the lumen with the opening through the inflation element and allows limited freedom of movement of the inflatable member with respect to the positioning element to allow a contacted organ to move according to its normal movements. Buckman, Jr. et al. discloses a toll for performing cardiac compression, which is antithetical to what is being accomplished by the present invention. Thus, Buckman, Jr. et al. wants a direct transfer of force from handle 76 to cup 84, so that a compression of the heart can be effected. The Examiner asserted that Buckman, Jr. et al. discloses methods for manipulating and position the heart, possibly during absence of clinically relevant hemodynamic instability. The Examiner referred to column 15, lines 12-14 and 34-48 for support for this assertion. C column 15, lines 12-14 and 34-48 of Buckman, Jr. et al. are portions of a description of a method for massaging the heart using the device of Buckman, Jr. et al. Compression of the heart by Buckman, Jr. et al. most definitely alters the hemodynamics of the heart compared to what they were prior to the compression.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1-2, 4, 6-11, 15-19, 25-30 and 35 (claims 5, 20-22, 24 and 32 having been canceled, without prejudice, above) under 35 U.S.C. Section 102(b) as being anticipated by Buckman, Jr. et al., U.S. Patent No. 5,484,391, as being no longer appropriate.

Claim 3 was rejected under 35 U.S.C. Section 103 as being unpatentable over Buckman, Jr. et al., U.S. Patent No. 5,484,391, in view of Heaven et al., U.S. Patent No. 5,337,754. It is respectfully submitted that claim 3 is allowable over this combination of references for at least the same reasons that claim 1 is allowable over Buckman, Jr. et al., since claim 3 depends from claim 1 and Heaven et al. does nothing to overcome the deficiencies of Buckman, Jr. et al. in meeting the recitations of claim 1.

Accordingly the Examiner is respectfully requested to reconsider and withdraw the rejection of claim 3 under 35 U.S.C. Section 103 as being unpatentable over Buckman, Jr. et al., U.S. Patent No. 5,484,391,

in view of Heaven et al., U.S. Patent No. 5,337,754, as being no longer appropriate.

Claims 12-14, 23 and 33 were rejected under 35 U.S.C. Section 103 as being unpatentable over Buckman, Jr. et al., U.S. Patent No. 5,484,391, in view of Peng et al., U.S. Patent No. 6,506,149. It is respectfully submitted that these claims are allowable over this combination of references for at least the same reasons that claims 1 and 25 are allowable over Buckman, Jr. et al., since each of these claims depends from one of claims 1 and 25, and Peng et al. does nothing to overcome the deficiencies of Buckman, Jr. et al. in meeting the recitations of claims 1 and 25. Further, with regard to claims 12-14, it would not have been obvious to provide the device of Buckman, Jr. et al. with an attachment element that allows normal movement of the organ and the cup with respect to the handle, since Buckman, Jr. et al. is designed to control the movement of the cup and the organ via the handle, by providing driving compression forces to the organ, via the handle. Provision of an attachment means as claimed would only provide more slop in the operation of the device of Buckman, Jr. et al., and therefore Buckman, Jr. et al. teaches away from the modification suggested by the Examiner.

Accordingly the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 12-14, 23 and 33 under 35 U.S.C. Section 103 as being unpatentable over Buckman, Jr. et al., U.S. Patent No. 5,484,391, in view of Peng et al., U.S. Patent No. 6,506,149, as being inappropriate.

Claim 31 was rejected under 35 U.S.C. Section 103 as being unpatentable over Buckman, Jr. et al. The Examiner is respectfully requested to reconsider and withdraw this ground of rejection as being moot, claim 31 having been canceled, without prejudice, above. Applicant does not acquiesce to this ground of rejection.

Claim 34 was rejected under 35 U.S.C. Section 103 as being unpatentable over Buckman, Jr. et al., U.S. Patent No. 5,484,391, in view of Taylor et al., U.S. Patent No. 5,906,607. The Examiner asserted that it would have been obvious to perform a coronary artery bypass procedure on a heart, using the device of Buckman, Jr. et al., since coronary bypass procedures are among the most common heart surgeries that require manipulation of the hear, ideally while still beating. Applicant respectfully disagrees. Taylor et al. discloses a stabilizer that is designed to perform coronary artery bypass surgeries on beating hearts. Taylor et al. teaches providing a surgical target area between stabilized areas of the beating heart that can be accessed to perform the coronary artery bypass surgery. Buckman, Jr. et al. provides no such surgical target area, since the cup 84 completely encloses the area that is surrounded by the regions of the cup that contact the organ. Accordingly, it is respectfully submitted that Buckman, Jr. et al. and Taylor et al. are not properly combinable in the way suggested by the Examiner. Further, Buckman, Jr. et al. is designed to massage the heart, not to stabilize it. Still further, even if these

Atty Dkt. No.:GUID-009

USSN: 09/118,132

references were properly combinable in the manner suggested by the Examiner, which it is respectfully submitted that they are not for the reasons provided above, the resulting combination would still not meet all of the recitations of claim 25, from which claim 34 depends, since the resulting combination would still not inflate an inflatable member and then apply a vacuum to the organ while maintaining the inflatable member in the inflated configuration.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim 34 under 35 U.S.C. Section 103 as being unpatentable over Buckman, Jr. et al., U.S. Patent No. 5,484,391, in view of Taylor et al., U.S. Patent No. 5,906,607, as being inappropriate.

Claims 36-38 and 40 were rejected under 35 U.S.C. Section 103 as being unpatentable over Buckman, Jr. et al., U.S. Patent No. 5,484,391. It is respectfully submitted that claims 36-38 and 40 are allowable over Buckman, Jr. et al. for at least the same reasons provided above with regard to claim 1, since these claims include all of the recitations of claim 1. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 36-38 and 40 under 35 U.S.C. Section 103 as being unpatentable over Buckman, Jr. et al., U.S. Patent No. 5,484,391, as being inappropriate.

Claim 39 was rejected under 35 U.S.C. Section 103 as being unpatentable over Buckman, Jr. et al., U.S. Patent No. 5,484,391, as applied to claim 35 above, and further in view of Peng et al., U.S. Patent No. 6,506,149. It is respectfully submitted that claim 39 is allowable over this combination or references for at least the same reasons as provided above with regard to claim 35, since Peng et al. does nothing to overcome the deficiencies of Buckman, Jr. et al. in meeting the recitations of claim 35. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim 39 under 35 U.S.C. Section 103 as being unpatentable over Buckman, Jr. et al., U.S. Patent No. 5,484,391, as applied to claim 35 above, and further in view of Peng et al., U.S. Patent No. 6,506,149, as being inappropriate.

It is further submitted that new claims 41-43 are all allowable over the art of record, since none of the art of record, whether taken alone or in any proper combination, discloses, suggests or teaches a device comprising: an inflatable member having an opening passing therethrough and an organ contacting portion surrounding a distal end of said opening; a first lumen connected to a proximal end of said opening and forming a fluid seal with said proximal end, said first lumen configured to deliver negative pressure through said opening; a second lumen fluidly connected to said inflatable member and not fluidly connected with said opening; and a positioning element connected to said inflatable member.

## Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number GUID-034.

Respectfully submitted,

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